The identification of phenotypes in patients with severe Chronic Obstructive Pulmonary Disease

Published: 19-05-2014
Last updated: 20-04-2024

Primary Objective: To identify new clinical phenotypes in patients with severe chronic obstructive pulmonary disease (COPD) using a cluster analysis.Secondary Objectives: To:- identify clinical phenotypes (based on e.g. lung function parameters,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON40211

Source
ToetsingOnline

Brief title
Phenotyping in COPD

Condition

- Respiratory disorders NEC

Synonym
Chronic Obstructive Pulmonary Disease (COPD), emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: COPD, Phenotypes

Outcome measures

Primary outcome

The main study parameter is the identification of new clinical phenotypes. The collected data will allow us to identify new phenotypes, clusters of patients with similar characteristics. These phenotypes are potentially based on a combination of lung function parameters, clinical parameters, radiologic parameters, and systemic parameters and genotypes and endotypes, in patients with severe COPD.

Secondary outcome

NA

Study description

Background summary

In patients with Chronic Obstructive Pulmonary Disease (COPD), the degree of airflow limitation itself does not adequately describe the complexity of COPD because significant heterogeneity exists between patients with respect to clinical presentation, physiology, imaging, response to therapy, decline in lung function and survival. Currently, a clear alternative for describing COPD does not exists but the identification of subgroups of COPD patients based on clinical or genetic factors (phenotypes) could be useful. The continuous flow of very severe COPD patients to the UMCG gives us the unique opportunity to perform a study on the phenotypes of very severe COPD and the underlying gene-environment interaction. We anticipate that the findings of this study will lead to an earlier identification of those subjects who are at risk to develop severe or very severe COPD. In addition, it will lead to a better clinical characterisation of established COPD, possibly enabling a more tailored treatment of different COPD subphenotypes.

Study objective

Primary Objective:
To identify new clinical phenotypes in patients with severe chronic obstructive pulmonary disease (COPD) using a cluster analysis.

Secondary Objectives:
To:
- identify clinical phenotypes (based on e.g. lung function parameters, clinical parameters, radiologic parameters, systemic parameters, pathological parameters and immunological parameters) in patients with severe COPD.
- identify endotypes/ intermediate phenotypes in patients with severe COPD.
- investigate the contribution of genotypes (including gene expression) in patients with severe COPD.

Study design

Observational cross-sectional study with a 2 phase design

Study burden and risks

This low risk study does not have individual benefits for the participating patients. Furthermore, the study will only take in total ± 2 extra hours and will be performed during regular visits. Hopefully, the identification of novel phenotypes will be useful for obtaining a more complete and realistic diagnosis and a more tailored approach in the management of patients with severe COPD.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Referral to the LVR intervention team or LTx team of the UMCG.
• Chronic Obstructive Pulmonary Disease (COPD) according the Global initiative for Chronic Obstructive Lung Disease (GOLD) criteria (post bronchodilator FEV1/FVC < 0.7)
• Written informed consent.

Exclusion criteria

There are no exclusion criteria for this study.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-08-2014
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO Date:	19-05-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL46286.042.14